510 (K) Summary
ComboWire™/ComboTip™ Pressure/Flow Guide Wire Family of Products

Date Prepared: October 21, 2004

Submitted by: Volcano Corporation
2870 Kilgore Rd.
Rancho Cordova, CA 95670

Contact person: Lorry W. Huffman
Director Regulatory Affairs

Phone number: (916) 638-9404 or (800) 228-4728 ext. 404
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Device Name: ComboWire™ and ComboTip™ Pressure/Flow Guide Wire Family of Products

Device classification:	**Class**
870.1330 – Catheter Guide Wire	II
870.2100 – Cardiovascular blood flow meters	II
870.2870 – Catheter tip pressure transducer	II
870.2890 – Vessel occlusion transducer	II
870.2900 – Patient Transducer and Electrical Cable	II

Predicate Device:

Predicate Wires Product Name	Predicate Wires 510(k) Clearance	Current Catalog Numbers
SmartWire® BrightWire (name is used in certain European countries due to trademark issues)	K021219	6400, 6400J, 6403, 6403J, 6413, 6413J 7400, 7400J, 7403, 7403J
FloWire®	K905411, K912776, K921563, K972762	1400, 1400J, 1401, 1401J, 1403, 1403J, 1404, 1404J, 1413, 1413J

Volcano Therapeutics Inc. purchased the assets of JOMED Inc. who had previously purchased Cardiometrics, Inc. under which K021219, K905411, K912776, K921563 and K972762 were filed.

Device Description:
The ComboWire™/ComboTip™ Pressure/Flow Guide Wire is a steerable guide wire with a pressure transducer mounted less than 3 cm proximal to the tip and a tip mounted ultrasound transducer. The ComboWire/ComboTip measures pressure and flow when used with the ComboMap™ Pressure/Flow Instrument, a class IIa currently marketed device. The ComboWire/ComboTip is currently available in a diameter of 0.014" with a length of 185cm however, additional sensor configurations and wire length will be produced in the future to accommodate customer needs just as has been done with SmartWire, WaveWire and FloWire where up to 10 models are offered. The proximal end of the ComboWire/ComboTip is compatible with the provided ComboWire/ComboTip Connector Cable Assembly. The ComboWire/ComboTip can be torqued using the included torque device to facilitate navigation through the vasculature.

Model Numbers and Accessories:

ComboWire™ Pressure/Flow Guide Wire	Model 9403
ComboTip™ Pressure/Flow Guide Wire	Model 9410

Table of Accessories Supplied with Device

Accessories
Torque Device
Connector Cable Assembly

Intended Use:
ComboWire™ and ComboTip™ Pressure/Flow Guide Wire is indicated for use to measure simultaneous pressure and blood flow velocities in blood vessels, including coronary and peripheral vessels, during diagnostic angiography and/or interventional procedures.

Device Technological Characteristics and Comparison to Predicate Device:
Currently pressure and flow velocity are measured with separate guide wires (SmartWire® or FloWire®), connected to separate systems (WaveMap® or FloMap®). The ComboWire and ComboMap combine the functionality of both technologies into one system. Material construction, measurement modalities and instrument connections are the same as the predecessor wires. The intended use and the fundamental scientific technology of the SmartWire and FloWire have not been altered and the same fundamental scientific technology has been incorporated into the ComboWire/ComboTip Family of products.

Performance Data:
Applicable testing was performed to evaluate the ComboWire™ and ComboTip™ Pressure/Flow Guide Wire. The test results were found to be acceptable as required by the respective test plans and protocols.

Conclusion:

The ComboWire™ and ComboTip™ Pressure/Flow Guide Wire Family of products have the same intended use and utilize the same fundamental scientific technology as that of the predicate devices. There are no new questions raised regarding safety and efficacy. The information provided in this Special 510(k) submission along with the *Declaration of Conformity with Design Controls* support a determination of substantial equivalence of the ComboWire™ and ComboTip™ Pressure/Flow Guide Wire Family of products to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 4 2004

Volcano Corporation
c/o Ms Lorry W. Huffman
Director, Regulatory Affairs
2870 Kilgore Rd.
Rancho Cordova, CA 95670

Re: K042996
Trade Name: ComboWire™ and ComboTip™ Pressure/Flow Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: II (two)
Product Code: DQX
Dated: October 18 , 2004
Received: November 01, 2004

Dear Ms. Huffman:

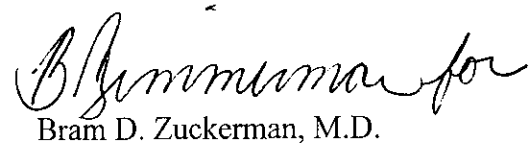
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K042996

Device Name: ComboWire™ and ComboTip™ Pressure/Flow Guide Wire

Indications for Use:

ComboWire™ and ComboTip™ Pressure/Flow Guide Wire is indicated for use to measure simultaneous pressure and blood flow velocities in blood vessels, including coronary and peripheral vessels, during diagnostic angiography and/or interventional procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use	OR	Over-the-Counter Use
X		
(Per 21 CFR 801.19)		

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K042996